

Remarks

Claims 1-13, 15-31, and 33-40 are pending in the subject application. By this Amendment, Applicant has canceled claims 1-13, 15-31, and 33-40 and added new claims 41-80. Support for the new claims can be found throughout the subject specification and in the canceled claims and the claims as originally filed. Entry and consideration of the amendments presented herein is respectfully requested. Accordingly, claims 41-80 are currently before the Examiner. Favorable consideration of the pending claims is respectfully requested.

As an initial matter, Applicant gratefully acknowledges the Examiner's withdrawal of the rejection under 35 USC §102(a), the withdrawal of certain of the previous rejections under 35 USC §112, second paragraph, and the withdrawal of the objection to the specification.

Applicant acknowledges the Examiner's withdrawal of claim 18 as being drawn to a non-elected invention. In the Office Action, the Examiner asserts that amended claim 18 is directed to a non-elected invention because the compound for downregulating the expression of *ebaf* was not limited to an *ebaf* compound, but was directed to a genus of compounds that downregulate *ebaf* expression. By this Amendment, claim 18 has been canceled.

Claim 39 is rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Applicant respectfully asserts that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that Applicant had possession of the claimed invention. Applicant gratefully acknowledges the Examiner's helpful suggestion concerning suitable claim language. By this Amendment, Applicant has canceled claim 39. New claim 70 corresponds, in part, to claim 39 and recites that the claimed peptide consists of the amino acid sequence shown in SEQ ID NO. 3. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 1-13, 15-26, 28-31, 33-38, and 40 are rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserts that there is inadequate

written description of variant *ebaf* sequences. Applicant respectfully asserts that there is adequate written description in the subject specification to convey to the ordinarily skilled artisan that they had possession of the claimed invention. By this Amendment, Applicant has canceled claims 1-13, 15-26, 28-31, 33-38, and 40, and has submitted new claims 41-80. Applicant respectfully asserts that the new claims submitted herewith find written description in the subject specification. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 1-28 and 40 are rejected under 35 USC §112, first paragraph, as nonenabled by the subject specification. While acknowledging that the subject specification does enable the utilization of serum and endometrial samples, and is enabled for antisera that specifically bind to *ebaf*, the Examiner asserts that the specification does not enable the determination of *ebaf* or variants thereof in samples such as brain tissue, urine, saliva, and feces. Applicant respectfully asserts that the claims are enabled by the subject specification. New claims 41, 49, 54, and 61-63 recite that the sample is from endometrial tissue, endometrial fluid, serum, saliva, or urine. As noted above, the Examiner acknowledges that endometrial samples and serum are enabled for the claimed invention. Applicant respectfully asserts that the claimed invention is also enabled for detection of *ebaf* protein in a sample of saliva or urine. Figure 21, which is described at page 17, line 32, through to page 18, line 9, of the subject specification, shows that *ebaf* protein was detected in saliva and urine of women using Western blot analysis. In addition, new claims 64-69 recite that the claimed antibody or antisera specifically binds to a protein encoded by *ebaf* or to a peptide having the amino acid sequence shown in SEQ ID NO. 3. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

Claims 1-3 are rejected under 35 USC §112, second paragraph, as indefinite for reciting claims limitations that do not define any specific type of reference sample or control. Claims 1-3 have been canceled by this Amendment. New claims 41-48, corresponding in part to canceled claims 1-3, specifically recite screening a sample for an abnormal level of an *ebaf* nucleic acid, or a protein encoded by an *ebaf* nucleic acid. Applicant respectfully asserts that an ordinarily skilled clinician, having the benefit of the teachings of the subject application, can determine whether a patient has normal or abnormal levels of an *ebaf* nucleic acid, or a protein encoded by an *ebaf* nucleic

acid, in a sample being tested. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims 10-12 are rejected under 35 USC §112, second paragraph, as indefinite for reciting "wherein" clauses that define specific diseases that are diagnosed. Claims 10-12 have been canceled by this Amendment. The new claims submitted herewith do not include claims that correspond to canceled claims 10-12. Accordingly, this rejection is moot. Reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claim 17 is rejected under 35 USC §112, second paragraph, as indefinite for not defining what components are in the diagnostic kit. Claim 17 has been canceled. The new claims submitted herewith do not include claims that correspond to canceled claim 17. Accordingly, this rejection is moot. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claim 18 is rejected under 35 USC §112, second paragraph, as indefinite on the grounds that essential reagents and method steps are missing. As noted above, claim 18 has been canceled by this Amendment. The new claims submitted herewith do not include claims that correspond to canceled claim 18. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claim 19 is rejected under 35 USC §112, second paragraph, as indefinite on the grounds that the method does not provide a correlation step of any results determined with the recited preamble, and that any level of *ebaf* would not determine endometrial receptivity, especially if the level of *ebaf* determined were indicative of an ovarian tumor (citing U.S. Patent No. 5,916,751). In addition, claims 20-23 are rejected under 35 USC §112, second paragraph, as indefinite on the grounds that no correlation methods steps defining what level of *ebaf* must be determined to correlate with the preamble of the claims have been set forth, nor have the urine or saliva samples been defined to be from a female. New claims 41-63, 72 and 73 specify that the samples are from a female animal and that the level in the sample of an *ebaf* nucleic acid or a protein encoded by *ebaf* is correlated with endometrial receptivity (or a lack thereof) of the female animal. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §112, second paragraph, is respectfully requested.

Claims 24-26 are rejected under 35 USC §112, second paragraph, as indefinite on the grounds that the claims do not define the object that has received treatment, "optimal treatment," how treatment is achieved, what suboptimal treatment would be, and what type of response to a treatment is being determined. The Examiner also asserts that the levels determined have not been correlated with the preamble of the claim, and that the urine, serum, or saliva samples have not been defined to have been obtained from a male or female animal. Claims 24-26 have been canceled. New claims specify that samples are from a female animal and that the female animal is the object of the method. The new claims also correlate the levels of *ebaf* or a protein encoded by *ebaf* with the diagnosis and prognosis of the female animal. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claim 27 is rejected under 35 USC §112, second paragraph, as indefinite as being directed to an "antiscra" "to *ebaf*." Claim 27 has been canceled and replaced by new claims 64-69 directed to an antibody or antisera. Applicant gratefully acknowledges the Examiner's helpful suggestion of suitable claim language. The new claims recite that the antibody or antisera specifically binds to a protein encoded by *ebaf* or to a peptide having the amino acid sequence shown in SEQ ID NO. 3. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claim 30 is rejected under 35 USC §112, second paragraph, as indefinite for reciting the phrase "by modulating", in light of the claim not positively reciting what type of modulation of *ebaf* is being carried out to correlate with the preamble of the claim. The Examiner also asserts that since no specific animal is recited in the claim, only *ebaf* is modulated, and, therefore, without a patient, fertility will not be modulated. Claim 30 has been canceled by this Amendment. New claims 72 and 73 recite methods for increasing or decreasing fertility of a female animal by decreasing or increasing, respectively, the level of an *ebaf* nucleic acid, or the activity of a protein encoded by an *ebaf* nucleic acid. Thus, the new claims positively recite the type of modulation (*i.e.*, increasing or decreasing expression of *ebaf*, or the production or activity of a protein encoded by *ebaf*) involved for increasing or decreasing fertility of a female animal. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claim 33 is rejected under 35 USC §112, second paragraph, as indefinite on the grounds that reagents of the kit are not distinctly claimed. Claims 34 and 36 are rejected under 35 USC §112, second paragraph, as indefinite in their recitation of the phrase "antisera and peptides as positive controls." Claim 35 is rejected under 35 USC §112, second paragraph, as indefinite for reciting the phrase "blotting test." Claims 33-36 have been canceled by this Amendment. New claims 74-80 recite specific elements of a kit. The new claims submitted herewith do not include claims that directly correspond to canceled claims 33-36. Accordingly, these rejections are moot. Accordingly, reconsideration and withdrawal of the rejections under 35 USC §112, second paragraph, is respectfully requested.

Claims 37 and 38 are rejected under 35 USC §112, second paragraph, as indefinite for reciting limitations directed to kits comprising "a PCR." Claims 37 and 38 have been canceled. New claim 80, which is directed to a kit containing reagents for PCR, recites distinct elements of the kit. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claim 40 is rejected under 35 USC §112, second paragraph, as indefinite for reciting claim limitations directed to a device for the detection of at least one variant of ebaf. Claim 40 has been canceled. None of the new claims submitted with this Amendment correspond to claim 40. Thus, this rejection is moot. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, second paragraph, is respectfully requested.

Claims 4-12, 15-17, 20, 21, 27-29, 31-38, and 40 are rejected under 35 USC §102(c) as anticipated by Tabibzadeh (U.S. Patent No. 6,294,662) or Tabibzadeh (U.S. Patent No. 5,916,751). The Examiner correctly notes that the patent application from which the '662 patent issued is a continuation of application Serial No. 08/919,421 from which the '751 patent issued. Applicant respectfully asserts that the cited U.S. patents do not teach or suggest the claimed invention. However, in any event, Applicant notes that international PCT application No. PCT/US99/09366, of which the subject application is the national stage filing under 35 USC §371, was filed while the '421 application was pending; thus, there is continuity of pendency between the applications. Applicant further notes that the subject application claims domestic priority under 35 USC §120 to the '421 application (now U.S. Patent No. 5,916,751). Thus, the subject application has the same

effective filing date as the '751 patent and the '662 patent and, therefore, the '751 and '662 patents are not prior art under 35 USC §102 against the subject application. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §102(e) is respectfully requested.

Claims 1-13, 15, 16, 19-26, 28, and 40 are rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the Examiner asserts that there is inadequate written description for the element "endometrial serum" recited in the claims. Claims 1-13, 15-31, and 33-40 have been canceled. None of the new claims submitted with this Amendment recite "endometrial serum." Thus, Applicant respectfully asserts the rejection is now moot. Accordingly, reconsideration and withdrawal of the rejection under 35 USC §112, first paragraph, is respectfully requested.

It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

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Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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